REMARKS

Claims 1-3, 7, and 9 are pending and under examination. The Applicants appreciatively note the Examiner's withdrawal of the obviousness rejection under the Langer and Udell references. In removing this rejection, the Examiner has indicated that the claims are free of the prior art.

The Examiner now rejects claims 1-3, 7, and 9 under 35 U.S.C. §112, first paragraph, as allegedly not being enabled. In particular, the Examiner argues that "Applicants have provided no support in the specification for the phrase 'independent of weight.'" (Final Office Action, *p.* 2). The Applicants must respectfully disagree.

In their response to the June 19, 2002, Office Action, the Applicants amended pending claim 1 to recite in pertinent part "A method of treating hypertension in humans, independent of weight loss, ..." Thus introducing the phrase in question to claim 1. The Applicants entered this amendment after Helen Nguyen, the former Examiner of record, indicated that doing so would move the case to allowance. (*See*, *p.* 3, June 19, 2002, Office Action). Note however, that the Applicants amended claim 1 "in order to further their business interests and the prosecution of the present application in a manner consistent with the Patent Business Goals (PBG),[1] and not in acquiescence to the Examiner's arguments and while reserving the right to prosecute the original (or similar) claims in the future." (*See*, Applicants' Response mailed September 19, 2002).

Prior to entering this amendment, the Applicants repeatedly requested that Examiner Nguyen consider and accord due weight to the Declaration of Drs. Dong and Ip, wherein the doctors stated that in their opinion "[t]he [Langer and Udell] references do not provide any teaching or suggestion of treating hypertension with CLA. . . . Our own research conducted after the filing of the above referenced application with materials provided by the applicants, indicates that the effect of CLA on blood pressure most likely occurs through the regulation of key enzymes." (Declaration of Drs. Dong and Ip, Appendix 2, Applicants' Response mailed February 4, 2002).

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[1] 65 Fed. Reg. 54603 (September 8, 2000).

In their Declaration, Drs. Dong and Ip stated the following regarding the combination of Langer and Udell:

> 3. We have read both of the cited references and conclude that the Examiner's reasoning regarding the Langer and Udell references is not based on sound scientific reasoning. The references do not provide any teaching or suggestion of treating hypertension with CLA. The Examiner's reasoning is scientifically flawed because a link cannot be drawn between the body composition altering effects of CLA described in Udell and the weak correlation between weight and hypertension described in Langer. Our own research, conducted after the filing of the above referenced application with materials provided by the applicants, indicates that the effect of CLA on blood pressure most likely occurs through the regulation of key enzymes. This research is described below.

Applicants respectfully remind the Examiner that she MUST consider and weigh all of the arguments and evidence presented by Applicants in each communication. The MPEP states that:

> **Office personnel should consider all rebuttal arguments and evidence presented by applicants**. . . . *In re Beattie*, 974 F.2d 1309, 1313, 24 USPQ2d 1040, 1042-43 (Fed. Cir. 1992). . . . **Office personnel should avoid giving evidence no weight**, except in rare circumstances. *Id. See also In re Alton*, 76 F.3d 1168, 1174-75, 37 USPQ2d 1578, 1582-83 (Fed. Cir. 1996).
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> A determination under 35 U.S.C. 103 should rest on **all the evidence** and should not be influenced by any earlier conclusion. *See, e.g., Piasecki*, 745 F.2d at 1472-73, 223 USPQ at 788; *In re Eli Lilly & Co.*, 902 F.2d 943, 945, 14 USPQ2d 1741, 1743 (Fed. Cir. 1990). Thus, once the applicant has presented rebuttal evidence, Office personnel should **reconsider** any initial obviousness determination in view of the entire record. *See, e.g., Piasecki*, 745 F.2d at 1472, 223 USPQ at 788; *Eli Lilly*, 902 F.2d at 945, 14 USPQ2d at 1743.

(MPEP § 2144.08; emphasis added). Indeed, the Applicants' right to have the Examiner consider all of the evidence of non-obviousness anew is especially true with regard to any fact based Rule 132 Declarations that the Applicants have submitted. The Applicants' right to

have their Rule 132 Declarations considered and responded to by the Examiner is well settled law. For instance, in the case of *In re Reuter*, the C.C.P.A. held that "[a]s long as there is a question of obviousness, no matter how trivial that question may seem, we think appellants have the right to have considered the Rule 132 affidavit." (*In re Orfeo*, 169 USPQ 487 (C.C.P.A. 1971); *See also*, *In re Reuter*, 210 USPQ 249 (C.C.P.A. 1981) (holding "[s]tatements [contained in a Declaration submitted by the Applicant] are probative and at a minimum, constitute expert opinion evidence.")).

Thus, any rejection of the claims as obvious over the combination of Udell and Langer must be reconsidered in light of the Ip and Dong Declaration. As stated in that Declaration, there is no sound basis for "drawing a link" between the disclosure of Udell and the" weak correlation between weight and hypertension described in Langer." This evidence has never been given consideration during the prosecution of this case and is completely separate from any considerations of controlling for weight loss, which is non-issue in the obviousness analysis.

The Examiner is well aware that there are three requirements, all of which must be met, in order to meet the evidentiary burdens requisite to establishing a *prima facie* case of obviousness. The first of these requirements is a suggestion or motivation, either in the references themselves, or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine their teachings. A recent Federal Circuit case explicitly discusses the standards for establishing motivation to combine. (*See, In re Lee*, 277 F.3d 1338 (Fed. Cir. 2002)). Specifically, the Federal Circuit held that:

> The factual inquiry whether to combine references must be thorough and searching. It must be based on **objective evidence** of record. **This precedent has been reinforced in myriad decisions, and cannot be dispensed with.**[2]

Furthermore, an Examiner may not simply rely on conclusory statements even for what they think might be common sense or well known in the art:

> The 'common knowledge and common sense' on which the Board relied in rejecting Lee's application are not the specialized knowledge and expertise contemplated by the Administrative Procedure Act. Conclusory statements such as those here provided do not fulfill the agency's obligation. This court explained in *Zurko*, 258 F.3d at 1385,

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[2] *See, In re Lee*, 277 F.3d 1338, 1344 (Fed. Cir. 2002); internal citations omitted; emphasis added.

> 59 USPQ2d at 1697 that 'deficiencies of the cited references cannot be remedied by the Board's general conclusions about what is 'basic knowledge' or 'common sense.' The Board's findings must extend to all material facts and must be documented on record, lest the 'haze of so-called expertise' acquire insulation from accountability. 'common knowledge and common sense,' even if assumed to derive from the agency's expertise, do not substitute for authority when the law requires authority.[3]

Regardless of the source of evidence, the Examiner's showing "must be clear and particular, and broad **conclusory** statements about the teaching of multiple references, standing alone, are not 'evidence'." (*In re Dembiczak*, 175 F.3d 994 (Fed. Cir. 1999); emphasis added). Thus, the Examiner's burden is to present clear and particular evidence that supports the combination or modification of the cited references.

In the present case, the Examiner has not rebutted the objective evidence presented in the Ip and Dong declaration, nor has the Examiner provided clear and particular evidence as to why the references should combined. In particular, the Ip and Dong declaration establishes that the correlation between weight loss and reduction in hypertension is "weak" and that there is no sound basis for combining Langer and Udell based on this "weak" correlation. Applicants respectfully note that this characterization of the correlation is not based on the suppositions of the declarants, but instead on the actual teachings of the reference itself. In fact, the Langer reference teaches at page 1133 that there is a "relatively weak relation between weight loss and blood pressure . . . ." Given this "relatively weak relation" Applicants fail to understand how the Examiner can make the leap from the effects of CLA on body composition to the use of CLA to treat hypertension. This is exactly the [point made in the declaration - one or ordinary skill in the art would not combine the references because there is no sound scientific basis for doing so.

As such, the current evidence of record establishes that there is no motivation to combine. Thus, the Examiner's prima facie case of obviousness stands rebutted and the claims should be passed to allowance.

CONCLUSION

It is respectfully submitted that the invention as claimed fully meets all requirements

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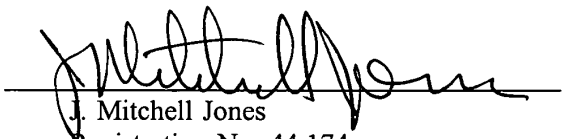
[3] *Id.* at 1344-1345.

for patentability and that the claims are worthy of allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

Dated: May 27, 2003



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Appendix 1

In The Claims:

Please amend claim 1 as follows:

1. (Twice Amended) A method of treating hypertension in humans[, independent of weight loss,] comprising:

a) providing a subject and a composition comprising a safe and effective amount conjugated linoleic acid; and

b) administering said conjugated linoleic acid composition to said subject under conditions such that blood pressure of said subjects is reduced.